

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

**IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION**

MDL No. 2326

THIS DOCUMENT RELATES TO:

KATHERINE L. HALL,

2:12-cv-08186

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

CAROLYN FRANCES SMOTHERS,

2:12-cv-08016

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

**BOSTON SCIENTIFIC'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION
TO EXCLUDE THE OPINIONS AND TESTIMONY OF VLADIMIR IAKOVLEV, M.D.**

INTRODUCTION

Dr. Vladimir Iakovlev obtained a medical degree straight out of high school in Russia before immigrating to Canada. He is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine, St. Michael's Hospital, Toronto. Dr. Iakovlev could be

credentialed to testify concerning pathology, but his opinions and testimony here should be excluded in their entirety.

Dr. Iakovlev's opinions here are not based on his review of any histological or gross evidence from Plaintiffs. Plaintiffs instead offer Dr. Iakovlev on subjects far beyond his field of expertise. Dr. Iakovlev should not be permitted to testify based on a study of 10 hernia mesh samples, particularly where he has made no final findings regarding (1) pain; (2) urinary symptoms; (3) mesh hardening, deformation, migration and formation of nodule/mass; and (4) mucosal erosions/ulcerations and postcoital bleeding. Dr. Iakovlev also lacks qualifications to render opinions on mechanical issues based on his ad hoc "stretch test." Likewise, Dr. Iakovlev should not be permitted to offer opinions that connect to the facts of these cases by nothing more than the *ipse dixit* of Dr. Iakovlev. Such opinions, without any reliable basis, will not assist the jury on any issues in these cases. Dr. Iakovlev's expert opinions on these particular topics fail to satisfy *Daubert's* gate-keeping standards. For this reason, and as more fully discussed herein, the Court should exclude Dr. Iakovlev's opinions on general causation, mechanical issues, and specific causation.

LEGAL STANDARD

The Federal Rules of Evidence and the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), require the trial judge, as a gatekeeper, to determine whether an expert's testimony is reliable and relevant. *Daubert*, 509 U.S. at 598; *Kumho Tire Co.*, 526 U.S. at 141; Fed. R. Evid.

702.¹ The proponent of expert opinion bears the burden of establishing its admissibility. *E.g.*, *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Under Federal Rule of Evidence 702, an expert opinion must satisfy three prerequisites before being admitted. First, the expert must be adequately qualified by virtue of “knowledge, skill, experience, training or education,” which is sufficiently related to the particular subjects at issue in the case. FED. R. EVID. 702; *See, e.g.*, *Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998). The offered expert opinion must not go “beyond the expert[’s] qualifications.” *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011).

Second, the expert’s opinion must assist “the trier of fact to understand the evidence or to determine a fact in issue.” FED. R. EVID. 702(a). Admissibility under this prerequisite requires “an analysis of whether the opinion is relevant to the facts at issue.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999). If the opinion “does not relate to any issue in the case,” it is inescapably “not relevant and ergo not helpful.” *Daubert*. 509 U.S. at 591. The question is “one of ‘fit,’” a quality that “is not always obvious.” *Id.* This requirement is, however, demanding. “[S]cientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Id.*

Further, the expert testimony must not be a mere regurgitation of factual information. *Hines*, 2011 WL 2680842, at *5. And expert testimony that “states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *United States v. McIver*,

¹ Federal law governs the admissibility of expert testimony in diversity actions. *E.g.*, *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005). In multidistrict litigation, the law of the transferee circuit governs on federal law. *E.g.*, *In re Temporomandibular Joint Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) (“In the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law.”).

470 F.3d 550, 562 (4th Cir. 2006). The expert must offer knowledge beyond the understanding of the average juror; testimony that will not assist the jury must be excluded. *Persinger v. Norfolk & W. Ry. Co.*, 920 F.2d 1185, 1188 (4th Cir. 1990) (affirming district court's exclusion of expert opinion because it "did no more than state the obvious.").

Third, the expert's opinion and methodology must be reliable and the expert must reliably apply the methodology to the facts of the case. *Daubert*, 509 U.S. at 592-3. "A bold statement of the experts' qualifications, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard." *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006). To be deemed reliable, the expert's opinion "must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. Gen. Motors Corp.*, 190 F. 3d 244, 250 (4th Cir. 1999). Most importantly, the expert testimony must be trustworthy. *Westberry*, 178 F.3d at 260. Expert witnesses must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152.

In determining the reliability of an expert opinion, *Daubert* provides the following factors for consideration: "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Smith & Nephew, Inc.*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592-94). These factors are "neither definitive, nor exhaustive." *Id.* at 199-200. In light of the variability of the analysis,

“the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Kumho Tire Co.*, 526 U.S. at 152.

Finally, a trial judge must remain cognizant “throughout an admissibility determination” of other applicable rules of evidence. *U.S. v. Dorsey*, 45 F. 3d 809, 813 (4th Cir. 1995). For example, regardless of its relevance, expert testimony must be excluded if its probative value is substantially outweighed by the danger of unfair prejudice. *Dixon v. CSX Transp., Inc.*, 990 F.2d 1440, 1452 (4th Cir. 1993).

Expert testimony can be “both powerful and quite misleading.” *Daubert*, 509 U.S. at 595. Where the proponent fails to establish all of the prerequisites, the exclusion of expert testimony is within the court’s sound discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).

AUTHORITIES AND ARGUMENT

I. DR. IAKOVLEV’S GENERAL CAUSATION OPINIONS SHOULD BE EXCLUDED BECAUSE THEIR BASIS IS UNRELIABLE.

Dr. Iakovlev purports to offer general causation opinions on morphological findings related to the complications of (1) pain; (2) urinary symptoms; (3) mesh hardening, deformation, migration and formation of nodule/mass; and (4) mucosal erosions/ulcerations and postcoital bleeding. He states that he bases his opinions on some 100 specimens of various types of explanted mesh for a study with Dr. Bendavid (“Bendavid Study”) to “investigate the morphological specifics of tissue before and after inguinal hernia surgery.” Rule 26 Expert Report of Dr. Vladimir Iakovlev (“Iakovlev Rep.”) at 1-2.^{2 3}

² A true and correct copy of Dr. Vladimir Iakovlev’s Report is attached to the Motion as Exhibit A.

³ In his deposition, Dr. Iakovlev also purported to base his opinions on confidential consulting expert work in litigation against another mesh manufacturer, and on 21 samples of Boston Scientific mesh on which he had no notes or summaries of any findings. Iakovlev Dep. 36:6-24;

A. Dr. Iakovlev's General Causation Opinions Based on the Bendavid Study are not Supported by Any Reliable Basis.

The methodology of the Bendavid study is questionable at best and does not support Dr. Iakovlev's opinions here. The Bendavid Study looks at tissue before and after inguinal hernia repair. Iakovlev Rep. at 1. The study is not confined to polypropylene mesh, but involves several other types as well. Dr. Vladimir Iakovlev's January 14, 2014 Deposition ("Iakovlev Dep. I") at 233:2-9.⁴ In fact, Dr. Iakovlev admits that transvaginally placed mesh is only a "fraction" of the examined explants. *Id.* at 51:2-7.

Dr. Iakovlev testified that the mesh explants he exams for the Bendavid Study are sent by Dr. Bendavid from another hospital. *Id.* at 231:9-12. Dr. Iakovlev provides no information on how the mesh explants are chosen for examination. And there is no discussion about the method of preparation of the mesh specimen or who even prepares the explants for examination. "Without any explanation of the method for selecting the explants or the potential error rate in the conclusions drawn from the explants, his opinions are not reliable and must be excluded." *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-0237, at *14 (S.D. W. Va. Jan. 15, 2014) (Judge Goodwin Memorandum Opinion and Order (Daubert Motions)); *See e.g., Smith & Nephew, Inc.*, 259 F.3d at 199 (observing that "whether a technique has a high known or potential rate of error and whether there are standards controlling its operation" is a factor guiding a district court's *Daubert* inquiry).⁵

42:18-45:1. Because Plaintiffs have not disclosed any related data, notes, or findings, Dr. Iakovlev should also be prohibited from testifying on any conclusions he has drawn from the same.

⁴ A true and correct copy of the transcript of Dr. Vladimir Iakovlev's January 14, 2014 Deposition is attached to the Motion as Exhibit B. Because only rough transcripts are available at this juncture, and in light of the deadlines in these matters, Boston Scientific will supplement the briefing on receipt of a final transcript.

⁵ These same problems should also preclude Dr. Iakovlev from testifying about mesh explants reviewed in his confidential consulting capacity in litigation against another manufacturer and about the 21 some mesh explants he reviewed for Boston Scientific.

Further, the Bendavid Study is not peer reviewed or published. Iakovlev Dep. I at 240:2-4. And the data has not been presented or shared at any conference. *Id.* at 241: 20-22. Specifically, Dr. Iakovlev states that one of the “new findings” stemming from the Bendavid Study is nerve ingrowth. Iakovlev Rep. at 2. However, such findings “. . . have not been published or described in literature.” Iakovlev Dep. I at 289:1-16. This study does not describe or support any relationship between pain and nerve ingrowth, and there are no such studies at this point, according to Dr. Iakovlev. *Id.* at 290:2-12. Moreover, the only final findings of the study at this juncture are based on 10 samples of hernia mesh. Iakovlev Dep. II at 8:8-21. Dr. Iakovlev’s general causation opinions based on the Bendavid Study are not subjected to peer review or publication and do not offer an explanation of methodology or consideration of a potential rate of error. *Smith & Nephew, Inc.*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592–94). Dr. Iakovlev’s general causation opinions are not “derived using scientific or other valid methods” that provide a reliable basis for forming said opinions and, therefore, they should be excluded. *See Oglesby*, 190 F.3d at 250.

Not only do these issues preclude Dr. Iakovlev from reliably relying upon the Bendavid Study as it relates to nerve ingrowth, Dr. Iakovlev’s study is not completed or final as it relates to (1) pain; (2) urinary symptoms; (3) mesh hardening, deformation, migration and formation of nodule/mass; or (4) mucosal erosions/ulcerations and postcoital bleeding—all of the subjects upon which he purports to offer opinions here. In order to offer opinions in these cases about the relationship between his morphological observations and Plaintiffs’ complaints, Dr. Iakovlev must make a “leap of logic” between his 10 hernia mesh sample study to some clinically significant endpoints. But these endpoints were not part of his study and the data is not there to

make the leap. *Doe*, 440 F. Supp. 2d at 470-71 (“A court may conclude there is simply too great an analytical gap between the data and the opinion proffered.”).⁶

II. DR. IAKOVLEV’S OPINIONS ON DEFORMATION BASED ON THE STRETCH TEST SHOULD BE EXCLUDED BECAUSE THEY ARE NOT SUPPORTED BY ANY RELIABLE BASIS

Dr. Iakovlev’s stretch test, which serves as the basis for his opinions on the effect of internal forces on deformation, is also unreliable. Dr. Iakovlev admits this testing method is not based on any testing standards, and does not have a written protocol. Dr. Vladimir Iakovlev’s January 15, 2014 Deposition (“Iakovlev Dep. II”) at 31:14-33:24.⁷ Dr. Iakovlev stretched mesh samples, but did not regulate or measure how much force he applied to the samples. *Id.* at 34:22-35:5. He set clamps on the mesh, but cannot provide measurements. His expressed intent was to stretch the mesh to reach 120% of the original length, but no one knows how Dr. Iakovlev arrived at that result or how his test could be repeated. *Id.* at 35:6-11. Dr. Iakovlev could not describe, nor seemingly comprehend, how he controlled his “test” for confirmation bias. *Id.* at 37:13-18. Dr. Iakovlev did not even wear gloves for the test. *Id.* at 31:14-33:24.

In addition, Dr. Iakovlev’s testing is not salient to the issues in this case, i.e., how mesh performs in the human body. Dr. Iakovlev reportedly intended his stretch test to represent how mesh performs inside the female pelvis. *Id.* at 35:23-36:5. Dr. Iakovlev testified he had no knowledge whether mesh responds outside the pelvis in the same way it does inside nor has he done mechanical testing on mesh in the body. *Id.* at 39:5-23. Dr. Iakovlev’s opinions founded on the stretch test are only based on an assumption that if the forces are similar, the behavior will be similar. *Id.* This is not a reliable basis, this is ipse dixit opinion proffered by the expert without

⁶ Throughout his deposition, Dr. Iakovlev also refused to answer questioning regarding subsequent phases of his research. To the extent Dr. Iakovlev also relies on any non-final, non-disclosed findings of his study, his opinions should also be excluded.

⁷ A true and correct copy of the transcript of Dr. Vladimir Iakovlev’s January 15, 2014 Deposition is attached to the Motion as Exhibit C.

supporting data. *Doe*, 440 F. Supp. 2d at 470. And Dr. Iakovlev testified that the test only measured unilateral forces, failing to measure forces from multiple directions or the amount of force used. Iakovlev Dep. II at 34:6-18. Further, Dr. Iakovlev had no knowledge of any general acceptance of his methodology in the scientific community. *Id.* at 37:4-7. Imprecise methodology does not provide valid inferences, failing to meet the *Daubert* standards. *Oglesby*, 190 F.3d at 250. Having no reliable basis, Dr. Iakovlev's stretch test should be excluded.

III. DR. IAKOVLEV'S OPINIONS ON DEFORMATION OF MESH BASED ON MESH DESIGN SHOULD BE EXCLUDED BECAUSE THEY ARE BEYOND HIS QUALIFICATIONS AND UNRELIABLE.

Dr. Iakovlev greatly oversteps the bounds of his education, training, and experience in providing opinions regarding mesh design and its relationship to mesh deformation. Dr. Iakovlev's opines on mesh design that "the different knitting pattern and heat treatment changes the qualities of the mesh and the pattern of deformation after stretching," are not based on reliable methodology and should be excluded. Iakovlev Rep. at 7. He opines that "the side [of the mesh] with knots has greater friction to the touch." *Id.* This assessment was reportedly made by palpating or touching the mesh. Iakovlev Dep. II at 17:13-19. Dr. Iakovlev also looked at the knitting pattern of the mesh to compare it to a "sweater," with a greater propensity for curling.

While a witness may be "qualified as an expert by knowledge, skill, experience, training, or education" (FED. R. EVID. 702), pathology is "the science of the causes and effects of diseases, especially the branch of medicine that deals with the laboratory examination of samples of body tissue for diagnostic or forensic purposes."⁸ There is nothing about Dr. Iakovlev's background in pathology that supports Dr. Iakovlev's qualifications to opine on mesh design.

⁸ Oxford dictionary, available at http://www.oxforddictionaries.com/us/definition/american_english/pathology.

While Dr. Iakovlev holds a medical degree specializing in pathology, he does not possess a degree in physics or engineering. *See* CV.⁹ Dr. Iakovlev also admits he has no experience or training in product design and development for the medical field. Iakovlev Dep. I at 156:7-10. Dr. Iakovlev did not obtain experience by reviewing design files for transvaginal mesh, let alone design files for the device at issue, the Obtryx. Dr. Iakovlev cannot point to a proposed, alternative design for Boston Scientific's polypropylene mesh products. Iakovlev Dep. II at 288:21-289:4. He has no prototypes or drawings of the same. *Id.* at 288:14-20 His opinions on curling are based on knitting patterns of clothing; however, he has no published literature to cite in support of such a comparison. *Id.* at 18:1-17. Dr. Iakovlev admits that his opinions on how heat treatment affects the performance of the mesh are simply from observations. *Id.* at 20:15-18. There is also an absence of studies comparing heat treated with non-heat treated mesh. *Id.* at 24:2-19. Without studies, Dr. Iakovlev is unable to correlate the clinical performance of mesh in women with heat treated devices. *Id.*

Dr. Iakovlev must limit his expert opinion to the specific area in which he possesses the knowledge, experience, and skill, specifically pathology. *See Smith v. Wyeth-Ayerst Labs. Co.*, 278 F.Supp. 2d 684, 697-98 (W.D.N.C. 2003) (barring physicians' purported expert testimony because "an expert, including physicians, must have specialized knowledge or skill in the specific area in which the testimony is proffered"); *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2001 WL 454586, at *19 (E.D. Pa. Feb. 1, 2001) (cardiologists "highly qualified within their particular disciplines" were not qualified to render opinions regarding regulatory standards, obesity, and the efficacy of the disputed drug where they did not treat obesity and one witness had not prescribed a diet drug.); *Alexander v. Smith & Nephew, P.L.C.*, 98 F.Supp. 2d 1287, 1292-93 (N.D. Okla. 2000) (granting motion to exclude expert testimony on a spinal

⁹ A true and correct copy of Dr. Vladimir Iakovlev's CV is attached to the Motion as Exhibit D.

fixation device from a family practitioner specializing in emergency medicine because “[t]he simple possession of a medical degree is insufficient”). Thus, Dr. Iakovlev is not qualified to offer opinions on mesh design, knitting, heat, and deformation, and those opinions should be excluded. *See Lab. Corp.*, 150 F.3d at 380-1.

IV. DR. IAKOVLEV’S OPINIONS ON POLYPROPYLENE DEGRADATION SHOULD BE EXCLUDED BECAUSE THEY ARE BEYOND HIS QUALIFICATIONS, UNRELIABLE, AND NOT HELPFUL TO A TRIER OF FACT.

A. Dr. Iakovlev is not Qualified to Render Opinions on Polypropylene Degradation.

Dr. Iakovlev again goes beyond his expert qualifications in his opinions on polypropylene degradation and they should be excluded. *See Hines*, No. 2:04-0690, 2011 WL 2680842, at *7. Dr. Iakovlev opines that Boston Scientific mesh degrades in the body and contributes to the failure mechanisms, such as mesh deformation and hardening. Iakovlev Rep. at 8; Iakovlev Dep. II at 81:13-82:3. Dr. Iakovlev does not possess a degree in biomaterials. *See generally* CV. Dr. Iakovlev has no training or experience in polymer science. Iakovlev Dep. I 152:18-22. He also admits he has no experience in polymers, testing the physical properties of polymers, or in determining the formulation to increase the durability of polymers. *Id.* at 161:18-162:7.

Dr. Iakovlev opines that the degradation occurs in the body and not in manufacturing. Iakovlev Rep. at 2. However, he readily admits he has no knowledge of the manufacturing process that Boston Scientific uses to create the mesh. Iakovlev Dep. I at 222:19-24. Dr. Iakovlev forms his opinions from a basic awareness of the manufacturing of mesh based on

either reading information online or a potential conversation with other experts, however, his recollection of where the basic knowledge came from is uncertain. *Id.* at 223:1-224:19.¹⁰

Dr. Iakovlev's opinions on polypropylene degradation are not based on "knowledge, skill, experience, training, or education." FED. R. EVID. 702. Therefore, he is not adequately qualified to opine on the subject and his opinions should be excluded. *See Hines*, 2011 WL 2680842, at *7.

B. Dr. Iakovlev's Expert Opinions on Polypropylene Degradation are not Supported by any Reliable Basis.

On degradation, Dr. Iakovlev's Expert Report cites observations and experimental studies showing polypropylene degradation. Iakovlev Rep. at 7. He discusses comparing three samples under SEM and TEM, including unused new mesh, mesh with one year of in-vivo exposure, and explanted mesh after nine years of in-body exposure. *Id.* at 8. The source of the examined mesh, however, is far from clear. Dr. Iakovlev testified that he studied explanted mesh—including the 21 Boston Scientific samples, but also other brands, in several different forms-slides, dry mesh, and formalin treated tissue—to evaluate alleged surface degradation. Iakovlev Dep. II 93:13-96:13. Dr. Iakovlev also does not cite any chemical testing he performed on the mesh to analyze the supposed degradation material for polypropylene properties. Iakovlev Dep. I at 156:11-14. Dr. Iakovlev admits there is no literature to cite to rely on appropriateness of using polarized light to evaluate potential degradation of polypropylene mesh or assessing polypropylene degradation in human tissue. Iakovlev Dep. II at 98:19-100:13. There is no reliable scientific basis for Dr. Iakovlev's opinions on polypropylene degradation, which should therefore be excluded.

¹⁰ As with many other subjects in his deposition, Dr. Iakovlev was instructed and declined to answer questioning on the specifics of 5 to 15 conference calls he had taken part in with other Plaintiffs' experts. Iakovlev Dep. I at 84:16-88:19. To the extent these conversations were not disclosed, Dr. Iakovlev should also be barred from offering opinions on their basis.

C. Dr. Iakovlev's Expert Opinions Polypropylene Degradation on Polypropylene will not Assist a Trier of Fact.

Dr. Iakovlev's opinions regarding polypropylene degradation also falter because they will not assist the trier of fact. At the most fundamental level, expert opinions must be based on the facts of the case. Fed. R. Evid. 702; *see e.g., Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony of highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion). Dr. Iakovlev's expert opinions are based on some 20 samples from non-bellwether plaintiffs. Iakovlev Rep. at 2. In fact, Dr. Iakovlev admits he does not have pathology from Plaintiffs to determine if there was evidence of surface degradation of the mesh. Iakovlev Dep. II at 115:10-19. Furthermore, Dr. Iakovlev was not able to correlate degradation to any clinical symptoms in Plaintiffs. *Id.* at 114:24-8. Without any application to the facts of the case, Dr. Iakovlev's opinions on mesh degradation will not assist the trier of fact, and therefore, should be excluded.

V. DR. IAKOVLEV'S SPECIFIC CAUSATION OPINIONS SHOULD BE EXCLUDED BECAUSE THEY ARE UNRELIABLE AND WILL NOT BE HELPFUL TO A TRIER OF FACT

Dr. Iakovlev also seeks to offer opinions on the specific causation of Plaintiffs' complaints. But the court should exclude Dr. Iakovlev's specific causation opinions because they are not reliable and will not be helpful to a trier of fact. Dr. Iakovlev's specific causation opinions are not relevant because they are not applied to the facts of the case as required by Rule 702 and *Daubert*, which will not assist the jury and therefore, should be excluded. With respect to relevancy, *Daubert* explains "[e]xpert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit" . . . Rule 702's "helpfulness" standard requires a valid scientific

connection to the pertinent inquiry as a precondition to admissibility. *Daubert*, 509 U.S. at 591-92 (internal citations and quotation marks omitted).

A. Dr. Iakovlev's Specific Causation Opinions are not Supported by any Reliable Basis

Dr. Iakovlev concludes that mesh caused Plaintiffs' alleged complications based on his supposed correlation of their symptoms with pathological findings seen in patients generally. Iakovlev Rep. at 11. These specific causation opinions are unreliable for several reasons. First, Dr. Iakovlev's opinions are based solely on his belief that when a patient receives mesh and subsequently has the type of complications allegedly experienced by Plaintiffs, it is the mesh that caused those complications. Iakovlev Dep. II at 323:9-327:21. For example, Dr. Iakovlev did not examine pathology from Ms. Smothers in order to determine if any pathological processes were at work, specific to Ms. Smothers; instead, he applies findings from mesh he examined from other patients. *Id.* at 232:18-24. In sum, Dr. Iakovlev opines that, because pathological findings (namely, nerve ingrowth) were present in 100% of mesh he examined from other patients, then they *must* be present in Ms. Smothers as well. *Id.* These are merely ipse dixit opinions with no scientific basis or methodology. *See Joiner*, 522 U.S. at 146 (holding that "nothing in *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert."); *Smith & Nephew, Inc.*, 259 F.3d at 202-203 (same).

B. Dr. Iakovlev Has No Histological or Gross Evidence for Plaintiffs To Support His Opinions.

Dr. Iakovlev's specific causation opinions are not based on pathology from the Plaintiffs, therefore any opinion in regards to a morphological assessment specific to Plaintiffs should be excluded. Dr. Iakovlev did not have pathology or morphological evidence for either Plaintiff.

Iakovlev Dep. II at 233:18-234:1. He did not physically examine either Plaintiff. *Id.* at 168:22-24; Dr. Iakovlev also admitted he never met or talked with Plaintiffs. Iakovlev Dep. I at 16:1-10.

Dr. Iakovlev admits there was “no available material for pathology assessment of the explanted mesh specimens of [Plaintiffs].” Iakovlev Rep. at 9. He cannot cite any histological or gross evidence for his far-flung opinions about Plaintiffs’ mesh: (1) distorting their bladders into hour-glass shapes, (2) curling, (3) deforming, (4) degrading, (5) becoming embrittled, (5) hardening, (6) acting on a reduced area of tissue attachment, (7) penetrating the bladder muscle or affecting autonomous bladder innervations, (8) compromising vascular supply, (9) entrapping nerves, or (10) attaching to muscles. *See generally* Iakovlev Rpt. at 10 -11. Dr. Iakovlev cannot reliably assess any pathological processes at work with Plaintiffs’ slings and draw reliable conclusions because he has not observed any histological or gross evidence (e.g., slides or samples) for Plaintiffs. Without this evidence, imaging, or examination, Dr. Iakovlev’s suppositions about what *may* be happening with the mesh in Plaintiffs’ bodies is mere conjecture. Dr. Iakovlev’s methodology in forming his specific causation opinions is not reliable and should be excluded. Further, because Dr. Iakovlev cannot offer histological or gross evidence that such pathological processes are at work in Plaintiffs, his testimony on the subject does not fit the facts of the case and must be excluded as irrelevant and unhelpful. *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-0237, at *11 (S.D. W. Va. Jan. 15, 2014) (Judge Goodwin Memorandum Opinion and Order (Daubert Motions))

C. Dr. Iakovlev’s Case-specific Opinions Should Be Excluded On His Failure to Perform a Differential Diagnosis and Rule Out Potential Alternate Causes

Finally, Dr. Iakovlev’s fails to make a reliable differential diagnosis in forming his specific causation opinions because he never considered alternative causes of Plaintiffs’ complications in his Expert Report. “Differential diagnosis, or differential etiology, is a standard

scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.” *Westberry*, 178 F.3d at 262. In fact, Plaintiffs stipulated at the January 15, 2014, deposition that Dr. Iakovlev did not perform differential diagnosis or rule out alternative causes. Iakovlev Dep. II at 224:4-8. Plaintiffs further went on to stipulate that Dr. Iakovlev would only testify as to the pathological process by which mesh could be causing Plaintiffs’ complaints *after* another doctor had isolated mesh as the cause. *Id.*

Dr. Iakovlev asserts in his Expert Report that the entirety of Plaintiffs’ complications are attributable to mesh design including: nocturia, frequency urination, urgency, incontinence, hesitancy on urination, vaginal bleeding, internal pain in lower abdomen and vagina, and dyspareunia. Dr. Iakovlev does not take into consideration whether the Plaintiffs suffered from these conditions pre-implant. *Id.* at 170:2-8. He also does not rule out the care and treatment provided by Plaintiffs’ treating physicians or any of Plaintiffs’ numerous other surgical procedures as a source of the alleged complications. *Id.* at 198:8-199:8.

Further, Dr. Iakovlev does not address patient specific factors that may have contributed to Plaintiffs’ complications, for instance, genetics or co-morbidities. He also admits he failed to explore the occurrence of pre-existing conditions that affect the speed of inflammatory response, including circulatory disorders, medications, or diabetes. Iakovlev Dep. I at 275:8-277:8. And Dr. Iakovlev reported he failed to assess whether Ms. Smothers’ discontinuance of her overactive bladder medication caused her urinary complications. Iakovlev Dep. II at 218:13-219:2.

Dr. Iakovlev’s specific causation opinions are based only upon his review of the Plaintiffs’ depositions and unspecified clinical records, all prepared by someone besides Dr. Iakovlev himself. Iakovlev Rep. at 9. For Ms. Hall, who has over a thousand pages of medical

records collected in this litigation, Dr. Iakovlev reviewed 5 pages of medical records.¹¹ For Ms. Smothers, who has over 800 pages of medical records collected in this litigation, Dr. Iakovlev reviewed 6 pages of medical records and 14 pages of Ms. Smothers' deposition testimony.¹² Dr. Iakovlev did not review or rely upon the depositions of *any* of Plaintiffs' treating physicians or 99% of the available medical records for them. Iakovlev Dep. II at 151:11-18; 152:2-15.

And Dr. Iakovlev testified that it was possible he did not review records dated prior to Ms. Smothers' implantation. *Id.* at 170:2-8. He admitted he has no knowledge of Ms. Smothers' incontinence, procedures, or attempts to treat incontinence before the surgery, only that she reported worsening incontinence after the surgery. Iakovlev Deposition I at 170:5-175:4.

Likewise, Dr. Iakovlev could not remember reviewing records of Ms. Hall's complaints, for example of dyspareunia, prior to the sling implant. Iakovlev Dep. II. At 316:12-22. Dr. Iakovlev testified that he did not review any records of Ms. Hall's over 300 emergency room visits. Iakovlev Dep. II. 314:4-8. Dr. Iakovlev also admits he reviewed no records regarding Ms. Hall's pain injections prior to her implant procedure. *Id.* at 314:9-17. Dr. Iakovlev, without pathology, is unable to determine the morphological changes the Plaintiffs had or still have. Iakovlev Dep. II at 217:4-13.

As but one example of the error caused by Dr. Iakovlev's subjective review and presupposed conclusions, Dr. Iakovlev opines that Ms. Hall experiences a painful, pulling sensation on the right side of her pelvis because of her Obtryx sling. He writes, "The effect can be compared to straight pulling of the entire scalp hair vs. angled pulling on a bundle of hair." He explains that the right-side asymmetry in Ms. Hall's symptoms means her symptoms were

¹¹ A true and correct copy of the Hall reliance materials disclosed by Plaintiffs are attached as Exhibit E.

¹² A true and correct copy of the Smothers reliance materials disclosed by Plaintiffs are attached as Exhibit F.

caused by “non-native” factors. Iakovlev Rep. at 10. But because Dr. Iakovlev pre-supposes Plaintiffs’ complaints were caused by mesh, does not review any pre-sling surgery records, and fails to consider or rule out alternative causes, he overlooks that Ms. Hall has suffered extreme, chronic, right-side pelvic pain, as well as dyspareunia, since at least the 1980s. Dr. Iakovlev fails to account for the fact Ms. Hall has been seen at the hospital, emergency room, and Boscobel Clinic over three-hundred times, pre-sling surgery, for this right-side “pulling” and “stabbing” pain. *See, e.g.*, Boscobel Clinic Records 199, 211; Wisconsin Hospital Records 95-96.¹³ Where an expert fails to identify a methodology but instead follows “a subjective conclusory approach,” the Court cannot even assess the methodology for reliability. *See Hoffman v. Monsanto Co.*, No. 2:05-CV-00418, 2007 WL 2984692, at *2 (S.D. W. Va. Oct. 11, 2007) (excluding an opinion where the expert followed “simply a subjective, conclusory approach that cannot reasonably be assessed for reliability”).

Dr. Iakovlev’s specific causation opinions should be excluded because he does not make a reliable differential diagnosis by ruling out alternative causes for Plaintiffs’ complications. *See In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 841 (S.D. W. Va. 2011) (excluding plaintiff’s expert because expert “did not adequately account for the many other conditions that might have caused [plaintiff’s] decline and death”); *Smith & Nephew, Inc.*, 259 F.3d at 202 (“[I]f an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert’s testimony.”). Dr. Iakovlev’s opinions on specific causation of Plaintiffs’ complications will not assist the trier of fact and should be excluded.

¹³ A true and correct copy of these excerpts of Ms. Hall’s medical records is attached as Exhibit G.

CONCLUSION

For these reasons, Boston Scientific respectfully requests this Court grant its Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 24, 2014, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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